

Remarks

Claims 25-35 and 37-45 are pending in the subject application. By this Amendment, Applicant has amended claim 25, canceled claims 26-28, 32, 35, 38, 39, and 42-45, without prejudice, and added new claim 46, which depends from claim 25. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Support for new claim 46 can be found throughout the subject specification and in claim 41. Entry and consideration of the amendments and new claim presented herein is respectfully requested. Accordingly, claims 25, 29-31, 33, 34, 37, 40, 41, and 46 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 38, 39, and 42 were withdrawn by the Examiner as directed to a non-elected invention. In Applicant's Amendment dated July 9, 2003, rejoinder of these claims was requested upon an indication of an allowable composition claim. However, in order to expedite prosecution of the subject application to allowance, the request for rejoinder of claims 38, 39, and 42 is hereby withdrawn and the claims have been canceled without prejudice to pursue in a continuing application.

Claims 25-35, 37, 40, 41, 43 and 45 are rejected under 35 USC §112, first paragraph, on the grounds that the subject specification does not provide sufficient written description so as to reasonably convey to the skilled artisan at the time the application was filed that the inventor had possession of the claimed invention. Specifically, the Examiner asserts there is insufficient written description for "a functional variant" of the homeodomain of antennapedia.

Applicant respectfully asserts that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that Applicant was in possession of the claimed invention at the time the application was filed. Applicant reiterates that the claims specify that the variants retain the functional ability of the antennapedia, *e.g.*, to permit translocation, and that page 10 of the subject specification refers to several publications which disclose additional variants of the antennapedia homeodomain. Therefore, Applicant respectfully asserts that the subject specification provides sufficient description as to a representative number of functional variants of the homeodomain of antennapedia that will be of utility in the present invention.

However, in order to expedite prosecution of the subject application to completion, Applicant has amended claim 25 to delete reference to functional variants. In accordance with the Doctrine of Equivalents and accepted principles of claim construction, Applicant respectfully asserts that the claims, as amended, are intended to cover functional variants of a homeodomain of antennapedia.

In view of the above, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 25-35, 37, 40, 41, 43, and 45 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. Under this rejection, the Examiner acknowledges that the subject specification enables a conjugate comprising a homeodomain of antennapedia and a second protein that is at least 100 amino acid in length, and optionally an amino acid tail that binds to an immobilized substrate. However, the Examiner asserts that the specification does not teach how to make or use a conjugate that is denatured or that comprises a nucleic acid in one region. Applicant respectfully asserts that the claims are enabled by the subject specification. In order to expedite prosecution of the subject application to completion, however, Applicant has amended claim 25 to specify that the conjugate is a fusion protein and that the second region consists of at least 100 amino acids. Support for these amendments can be found in canceled claims 28 and 44. Applicant has also amended claim 25 to recite that the first and second region of the claimed conjugate are not denatured.

In another aspect of this rejection, the Examiner states that “. . . the state of art at the time of filing [the subject application] considers gene therapy as a highly unpredictable field.” The Examiner seems focused on the utility of the claimed invention as involving gene therapy. Although use of the invention for delivery of nucleic acids to a cell for therapeutic purposes is a utility of the invention (and Applicant maintains such utility is enabled), it is not the only utility of the invention, as Applicant has previously pointed out. Applicant maintains that the invention can be used for things such as delivery of a protein of interest or a reporter gene in a cell (*e.g.*, see page 12, lines 13-14, of the subject specification). The subject invention can also be used to generate an immune response (humoral and cellular) against an antigen (*e.g.*, see page 13, lines 8-17, of the subject specification). Applicant respectfully asserts that the invention is enabled for all such uses. As the Examiner is undoubtedly aware, when an Applicant is claiming a composition of matter, Applicant

need only teach how to make and how to use the invention for any single utility and the enablement requirements of 35 USC §112, first paragraph, are met.

In view of the above, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.


It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position under any of the rejections.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

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